

EXHIBIT F

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re:
Bair Hugger Forced Air Warming
Products Liability Litigation

This Document Relates To:

All Actions MDL No.
15-2666 (JNE/FLM)

VIDEOTAPED DEPOSITION

OF

CHRISTOPHER NACHTSHEIM

Minneapolis, Minnesota

Tuesday, November 29, 2016

Reported by:
Amy L. Larson, RPR
Job No. 113495

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1 NACHTSHEIM
2 INDEX:
3 EXAMINATION BY: PAGE
4 Ms. Garcia.....8, 372
5 Mr. Sacchet.....254
6 EXHIBITS MARKED FOR IDENTIFICATION:
7 Exhibit 1.....10
8 Acknowledgment and Agreement to be Bound
9 No Bates
10 Exhibit 2.....10
11 Notice of Videotaped Deposition of
12 Christopher Nachtsheim
13 No Bates
14 Exhibit 3.....12
15 Christopher Nachtsheim, Ph.D.,
16 Curriculum Vitae
17 No Bates
18 Exhibit 4.....15
19 Forced-Air warming and ultra-clean
20 ventilation do not mix
21 No Bates
22 Exhibit 5.....15
23 Patient Warming Excess Heat:
24 The Effects on Orthopedic Operating
25 Room Ventilation Performance
No Bates
Exhibit 6.....29
Statistical Analysis for HPS Protocol 003
Bates Albrecht_0016008 - Albrecht_0016012
Exhibit 7.....34
Research Agreement
Bates Belani_000054 - Belani_000061
Exhibit 8.....37
Logistic Regression -
Mark Albrecht - March 11, 2016
Bates Albrecht_0002275 - Albrecht_0002278

1 NACHTSHEIM
2 INDEX: (Cont'd.)
3 EXHIBITS MARKED FOR IDENTIFICATION: PAGE
4 Exhibit 9.....38
5 11/1/2013 E-mail Chain
6 Subject: Re: Analytically speaking
7 Bates Albrecht_0000101 - Albrecht_0000102
8 Exhibit 10.....53
9 3/24/10 E-mail Chain
10 Subject: First Publication I'd Like to
11 Include you on
12 Bates Nachtsheim_0000364 - Nachtsheim_0000382
13 Exhibit 11.....58
14 April 2010 E-mail Chain
15 Subject: Testing
16 Bates Nachtsheim_0001408 - Nachtsheim_0001410
17 Exhibit 12.....62
18 4/8/10 E-mail
19 Subject: Update on testing
20 Bates Nachtsheim_0001571
21 Exhibit 13.....78
22 4/9/10 E-mail
23 Subject: Problem with laminar flow lab
24 Bates Nachtsheim_0000832 - Nachtsheim_0000833
25 Exhibit 14.....84
April 2010 E-mail Chain
Subject: Update
Bates Nachtsheim_0001545 - Nachtsheim_0001547
Exhibit 15.....95
May 2010 E-mail Chain
Subject: Abstract "crud and bug"
!!!Important!!!
Bates Nachtsheim_0000118 - Nachtsheim_0000120
Exhibit 16.....100
5/29/10 E-mail
Subject: Both abstracts,
Statistical files and data files
Bates Nachtsheim_0000191 - Nachtsheim_0000192,
Nachtsheim_0000211 - Nachtsheim_0000223

1 NACHTSHEIM
2 INDEX:
3 EXHIBITS MARKED FOR IDENTIFICATION: PAGE
4 Exhibit 17.....114
5 July 2010 E-mail Chain
6 Subject: Manuscript drafts for meeting
7 Bates Nachtsheim_0000548 - Nachtsheim_0000549,
8 Nachtsheim_0000556 - Nachtsheim_0000576,
9 Nachtsheim_0000600 - Nachtsheim_0000608,
10 Nachtsheim_0000577 - Nachtsheim_0000599,
11 Nachtsheim_0000613 - Nachtsheim_0000615
12 Exhibit 18.....146
13 7/8/10 E-mail
14 Subject: Arizant FDA Warning Ltr
15 Bates Nachtsheim_00000385
16 Exhibit 19.....188
17 1/4/11 E-mail Chain
18 Subject: Article I was talking about
19 Bates Nachtsheim_0000177 - Nachtsheim_0000179
20 Exhibit 20.....192
21 December 2010/January 2011 E-mail Chain
22 Subject: Rough Copy
23 Bates Nachtsheim_0001110 - Nachtsheim_0001115,
24 Nachtsheim_000127 - Nachtsheim_000130,
25 Nachtsheim_0001199 - Nachtsheim_0001201,
Nachtsheim_0001206
Exhibit 21.....195
Forced Air Warming versus Conductive
Fabric Warming - An Evaluation of
Laminar Operating Room Ventilation Disruption
Bates Nachtsheim_0001206 - Nachtsheim_0001229
Exhibit 22.....205
Implementing Effective SSI Surveillance
No Bates
Exhibit 23.....226
1/25/11 E-mail Chain
Subject: Minor Changes and a Query
Bates Nachtsheim_0000750 - Nachtsheim_0000751,
Nachtsheim_0000727 - Nachtsheim_0000749

Page 6

1	NACHTSHEIM	
2	INDEX: (Cont'd.)	
3	EXHIBITS MARKED FOR IDENTIFICATION: PAGE	
4	Exhibit 24.....231	
5	January 2011 E-mail Chain	
6	Subject: Papers you are involved in	
7	Bates Nachtsheim_0000819 - Nachtsheim_0000821	
8	Exhibit 25.....277	
9	April 2015 E-mail Chain	
10	Subject: Statistical Practitioners Forum:	
11	Advanced DOE Class	
12	Bates 3MBH01293497 - 3MBH01293499	
13	Exhibit 26.....322	
14	Doctor Says a Device He Invented	
15	Poses Risks	
16	No Bates	
17	Exhibit 27.....333	
18	Table	
19	Bates Albrecht_0002298	
20	Exhibit 28.....341	
21	Would Complications Following Rivaroxaban	
22	Administration - A Multi-Centre Comparison	
23	with Low Molecular Weight Heparin for	
24	Thromboprophylaxis in Lower Limb	
25	Arthroplasty	
	Bates Nachtsheim_0000451 - Nachtsheim_0000466	
	Exhibit 29.....369	
	Forced-Air Warming Does Not Worsen Air	
	Quality in Laminar Flow Operating Rooms	
	Bates 3MBH00985628 - 3MBH00985633	
	Exhibit 30.....377	
	Curriculum Vitae	

Page 7

NACHTSHEIM

THE VIDEOTAPED DEPOSITION OF CHRISTOPHER NACHTSHEIM, taken on this 29th day of November, 2016, at the Law Offices of Faegre Baker Daniels, LLP, 2200 Wells Fargo Center, 90 South Seventh Street, Minneapolis, Minnesota, commencing at approximately 9:11 a.m.

P R O C E E D I N G S

THE VIDEOGRAPHER: This is the Start of tape labeled number 1 of the videotaped deposition of Christopher Nachtsheim in the matter of In Re: Bair Hugger Forced Air Warming Products Liability Litigation in the U.S. District Court for the District of Minnesota, Case Number 15-2666 (JNE/FLM).

This deposition is being held at the Faegre Baker law firm in Minneapolis, Minnesota, on November 29th, 2016. We are going on the record at 9:11 a.m. My name is Kraig Hildahl, I'm the legal video specialist from TSG Reporting. The court reporter is Amy Larson also in association with

Page 8

NACHTSHEIM

TSG Reporting.

Will counsel please introduce themselves for the record.

MS. GARCIA: Christin Garcia, counsel for defendants 3M and Arizant.

MS. LEWIS: Deborah Lewis also counsel for defendants 3M and Arizant.

MR. SACCHET: Michael Sacchet for plaintiffs.

THE VIDEOGRAPHER: Will the court reporter please swear in the witness and then we can proceed.

CHRISTOPHER NACHTSHEIM, a witness in the above-entitled action, after having been first duly sworn, was deposed and says as follows:

EXAMINATION

BY MS. GARCIA:

Q. Hello, Professor Nachtsheim.

A. Hello.

Q. Thank you for coming here today. Could you start by, for the record, just providing your

Page 9

NACHTSHEIM

full name and spell your last name and let us know your address.

A. Christopher John Nachtsheim. And it's N as in north, A-C-H-T, S as in Sam, H-E-I-M. Address is 1789 Summit Avenue, St. Paul, Minnesota 55105.

Q. Thank you. Have you ever been deposed before?

A. Yes.

Q. Okay. The one rule of deposition I just want to reinforce today is if you have any difficulty understanding -- well, if you don't understand my question, if you would like me to clarify something, will you please let me know that?

A. Uh-huh. Yes.

Q. Yes?

A. Yes.

Q. There's rule number 2.

A. That's rule number 2, I knew that.

Q. You will need to say things out loud so that we can get an accurate transcription of the record in writing where your head movements can't be taken down, and then we will try not

Page 330

NACHTSHEIM

object to the form of the question.

THE WITNESS: I -- I read this --

MR. SACCHET: I can walk through it slower.

THE WITNESS: Well, I read this to say that in March 2009 there was a change to the combination of the two drugs you've pronounced, and I don't believe there were any changes until the end of the study.

MR. SACCHET: Okay.

BY MR. SACCHET:

Q. So -- so we're clear, there was a period in which Gentamycin was applied to some forced-air warming patients, and then the antibiotic changed to a combination of Gentamycin and Teicoplanin that applied to some forced-air warming patients and all of the conductive fabric warming patients, correct?

A. Correct.

Q. Assuming the change in antibiotic did not affect infection rates between warming devices, would you still consider the antibiotic a confounding variable?

Page 331

NACHTSHEIM

MS. GARCIA: Object to the form of the question.

THE WITNESS: I'm going to assume that it has -- the change had no effect?

BY MR. SACCHET:

Q. Yeah, assume that the antibiotic had no effect on the infection rate. Would it still be a confounding variable?

MS. GARCIA: Object to the form of the question.

THE WITNESS: I don't think it would be -- I don't think it would be considered a confounding variable. I'm trying to think of how else it might have an impact, if it's not having an effect. I guess it -- no, I don't think it would be, yeah.

BY MR. SACCHET:

Q. One way that we could control for the -- let me strike that.

In order to determine whether the antibiotic had an effect on infection rates, we could control for the warming device --

A. Yes.

Page 332

NACHTSHEIM

Q. -- and evaluate whether infection rates between the changed antibiotic stayed the same or went up or down --

A. Correct.

Q. -- with that control device, correct?

A. (Nods head.)

MS. GARCIA: I'm going to object to the form of the question.

BY MR. SACCHET:

Q. Did you understand it?

A. Yes.

Q. If infection rates between the two groups were similar, that would tend to show that the antibiotic was not a confounding factor?

A. Correct.

MS. GARCIA: Object to the form of the question.

BY MR. SACCHET:

Q. Assume that Mr. Albrecht, who you previously mentioned was an expert in statistics and you had full confidence in his ability to analyze data presented in this article, informed you that he found a 2.8 percent infection rate in those who received Gentamycin, a single drug,

Page 333

NACHTSHEIM

but 3.1 percent of patients who received the combination of antibiotics, but also forced-air warming patients, with a nearly identical infection rate, would you determine that the antibiotic was a confounding factor?

MS. GARCIA: Object to the form of the question.

THE WITNESS: That would be strong evidence that it was not a confounding factor.

MR. SACCHET: Let's mark this. (Whereupon, Exhibit 27 was marked for identification.)

BY MR. SACCHET:

Q. So just to be clear, if we look at this table that's presented here, we can see in the first line it presents antibiotic protocol 1 versus 2 for FAW, does it not?

A. It does.

Q. Assume that protocol 1 is the singular antibiotic, i.e. Gentamycin, and that protocol 2 is the combination of Gentamycin and Teicoplanin.

A. Uh-huh. Yes.

Page 334

NACHTSHEIM

Q. In this particular analysis, forced-air warming is held constant, correct?

A. Correct.

Q. And for forced air, protocol 1, the percent of patients developing infection was 2.8?

A. Correct.

Q. And for forced air, protocol 2, involving patients who received both Gentamycin and Teicoplanin, the infection rate was 3.1, correct?

A. Correct.

Q. And the p-value was 0.839, correct?

A. That's what's reported here.

Q. That's what's reported here. We could conclude, based on this data set of these numbers, that when the patient-warming device is held constant, that the change in antibiotic had no effect on infection rates, correct?

MS. GARCIA: Object to the form of the question.

THE WITNESS: Assuming there's sufficient power in those sample sizes, although they look fairly large to me, yes.

Page 335

NACHTSHEIM

BY MR. SACCHET:

Q. The patient population for forced-air protocol 1 was 389 patients, correct?

A. Correct.

Q. And the patient population for those receiving the combination was 678, correct?

A. Correct.

Q. Those are fairly large patient populations, correct?

A. Correct.

MS. GARCIA: Object to the form of the question.

BY MR. SACCHET:

Q. Another way to determine whether the antibiotic was a confounding variable would be to control the antibiotic, but evaluate different infection rates between different forced-air -- or different warming devices, correct?

A. Yes.

MS. GARCIA: Object to the form of that question also.

BY MR. SACCHET:

Q. And if the infection rates were still higher

Page 336

NACHTSHEIM

among those who received forced-air warming compared to those who received conductive fabric warming, that would tend to show the antibiotic did not substantially affect infection rates, correct?

A. Correct.

MS. GARCIA: Object to the form of the question.

BY MR. SACCHET:

Q. And if that's true, the change in antibiotic would also not be a confounding factor, correct?

A. Correct.

MS. GARCIA: Object to the form of the question.

BY MR. SACCHET:

Q. If I could --

MR. SACCHET: Could I ask your basis for the objection?

MS. GARCIA: I'm sorry?

MR. SACCHET: Could I ask your basis for the objection on form?

MS. GARCIA: Yes. You keep using the word, "determine," and you keep using the

Page 337

NACHTSHEIM

word, "show," and you keep using the word, "establish," and I'm objecting to the form of the question based on those terms.

MR. SACCHET: That's not going to pass muster in the court.

BY MR. SACCHET:

Q. As to the hypothetical I just presented, if you could turn your attention to the second line of the table.

MS. GARCIA: I'm sorry, to just be complete with my form objection, it's also an incomplete hypothetical.

MR. SACCHET: Fair enough.

BY MR. SACCHET:

Q. Antibiotic protocol 2 involved a combination have Gentamycin and Teicoplanin, correct?

MS. GARCIA: Object to

foundation --

BY MR. SACCHET:

Q. -- for the sake of --

A. Yes.

MS. GARCIA: Excuse me. Object to foundation for that.

BY MR. SACCHET:

NACHTSHEIM

Q. And the data here shows that 3.1 percent of patients who received forced-air warming in the combination antibiotic developed joint infections, correct?

A. Correct.

Q. Whereas, .9 percent of patients who received conductive fabric warming and the combination of antibiotics developed joint infections, correct?

A. Correct.

Q. By holding the antibiotic constant and discontinuing the use of forced-air warming, that resulted in a 71 percent decrease in joint infections, did it not?

MS. GARCIA: Object to the form of the question.

THE WITNESS: Yes, it did.

BY MR. SACCHET:

Q. That essentially matches the 73 percent decrease in infections that was noted in the McGovern article itself, does it not?

A. Correct.

MS. GARCIA: Object to the form of the question.

NACHTSHEIM

BY MR. SACCHET:

Q. And based on the p-value of .0008, which is far less than .05, you would determine that difference to be statistically significant, would you not?

A. I would.

Q. So whether we control for the device or control for the antibiotic, based on this data set in Exhibit 27, would you determine that the antibiotic was not a confounding factor?

MS. GARCIA: Object to the form of the question, it's a lack of foundation, it's an incomplete hypothetical.

THE WITNESS: This data certainly supports that hypothesis.

BY MR. SACCHET:

Q. And if it were not a confounding factor, would there be any reason to deselect patients from the population of 1,437 accounted for in the McGovern study in order to exclude those who received a single antibiotic?

A. No.

NACHTSHEIM

MS. GARCIA: Object to the form of the question.

BY MR. SACCHET:

Q. And if we were to do that and reduce the population, let's say, from the 1,473, or 37, I've forgotten which number it is, down to a number of let's say 500 patients, there could be concern about the powering of that population?

A. There could. There could be.

Q. Another confounding factor that was discussed this afternoon was a change in the thromboprophylaxis protocol, correct?

A. Yes. Can -- can you just remind me where that --

Q. Yeah, if we could turn to page 1540.

A. (Complies.)

Q. If you look at the bottom of the first full paragraph in the left-hand column, it states the thromboprophylaxis regimen from July 2008 to the end of July 2009 was Tinzaparin.

A. Uh-huh.

Q. Then it says from August 2009 to February

NACHTSHEIM

2010, Rivaroxaban, which I'll represent is otherwise known as Xarelto, was provided from day one, but in February 2010 to the end of this study, patients were reverted to Tinzaparin, correct?

A. Yes.

Q. Assuming the change in the prophylaxis did not affect infection rates during the time of this study, i.e., Exhibit 4, would you still consider it a confounding variable?

A. No.

MS. GARCIA: Object to the form of the question.

(Whereupon, Exhibit 28 was marked for identification.)

MS. GARCIA: What number are we on?

MR. SACCHET: Twenty-eight, I believe.

THE COURT REPORTER: Correct.

MS. GARCIA: Thank you.

BY MR. SACCHET:

Q. Have you seen this document before, Professor?

Page 346

NACHTSHEIM

p-value was a statistically significant value, correct?

A. Yes, correct.

Q. So there were fewer wound complications as a result of the use of a low weight molecular heparin --

A. Correct.

Q. -- compared to Rivaroxaban, correct?

A. Yeah, correct.

MS. GARCIA: Object to the form of the question.

BY MR. SACCHET:

Q. However, the study notes that rates for RTT, which we established to be a return to theater for --

A. Uh-huh.

Q. -- infections, were not significantly different; do you see that?

A. Correct. Yes, I do.

Q. Assuming the truth -- well, let me back up.

Would you also agree that the McGovern study, Exhibit --

MS. GARCIA: Four.

BY MR. SACCHET:

Page 347

NACHTSHEIM

Q. -- 4, evaluated joint infections?

A. Yes.

Q. It did not evaluate wound complications, did it?

A. Correct, it did not.

Q. Assuming the truth of this study, would you ultimately agree that the change in protocol from Tinzaparin, which is an LMWH, to Xarelto, otherwise known as Rivaroxaban, and then back to Tinzaparin, did not significantly affect the infection rate?

MS. GARCIA: Object to the form of the question, to lack of foundation, and it's an incomplete hypothetical.

THE WITNESS: Assuming the study was carefully done and generalizable, yes.

BY MR. SACCHET:

Q. And assuming the study was well done and generalizable, would you agree that the change in thromboprophylaxis noted in the McGovern study, Exhibit 4, did not confound the infection rates?

MS. GARCIA: Object to the form of the question.

Page 348

NACHTSHEIM

THE WITNESS: Assuming -- yes.

BY MR. SACCHET:

Q. And would you also conclude that, assuming the truth of this study, it would be improper to deselect all of the patients who received Xarelto, otherwise known as Rivaroxaban, from the patient population if the thromboprophylaxis was not a confounding variable?

MS. GARCIA: Object to the form of the question.

THE WITNESS: It doesn't seem justified in -- on the basis of these results.

BY MR. SACCHET:

Q. And, in fact, when the coauthors of the McGovern study were in the process of publication, are you aware that at numerous times they sought to collect additional data in support of the study?

A. I was not aware of that. I knew that -- I knew that they sought to run this study out in time.

Q. Are you aware that when Mr. Albrecht and

Page 349

NACHTSHEIM

Dr. Reed collected additional data that went beyond January 2011 in the conductive fabric warming population, that the data still showed a significant decrease in infections when conductive fabric warming was used?

A. I'm aware of that.

Q. Assuming that --

MS. GARCIA: Can we take a break shortly?

MR. SACCHET: Yeah, give me two minutes.

BY MR. SACCHET:

Q. Assuming that neither the antibiotic nor the thromboprophylaxis protocol required control because they were not confounding factors as we discussed, you would be confident in the results of the observational study presented in the McGovern data?

MS. GARCIA: Object to the form of the question.

THE WITNESS: I'm confident that those weren't confounding factors, that those studies are well done. It doesn't rule out the potential for other confounding factors.

Page 350

NACHTSHEIM

MR. SACCHET: Fair enough.

BY MR. SACCHET:

Q. And you continue to stand by the results of the observational studies --

A. Yes.

Q. -- in the McGovern publication?

A. I do.

MR. SACCHET: Let's take a break.

THE VIDEOGRAPHER: We're going off the record at 5:07 p.m.

(Whereupon, a brief recess was taken.)

THE VIDEOGRAPHER: This is video number 6 in the deposition of Christopher Nachtsheim. Today is November 29th, 2016. We're going back on the record at 5:18 p.m.

BY MR. SACCHET:

Q. Professor Nachtsheim, if we could turn to Exhibit 5, which is the Belani study.

A. I have it.

Q. Great. And as to this study, your role was to exclusively review the statistical portion of this study, correct?

A. Correct.

Page 351

NACHTSHEIM

Q. You had no involvement in the setup of the experiment?

A. I did not.

Q. You had no role in the execution of the physical experiment?

A. I did not.

Q. You had seen, whether by video or in person, disruption of laminar flow caused by the Bair Hugger before, correct?

A. I had, yes.

MS. GARCIA: I'm sorry, can I hear that question again? I was thinking and I did not hear the question.

MR. SACCHET: Can you -- do you mind repeating it.

(Whereupon, the last question was read by the court reporter.)

MS. GARCIA: Object to the form of the question, asked and answered.

BY MR. SACCHET:

Q. So you were familiar with the possibility, based on your personal experience, that the Bair Hugger could disrupt laminar airflow, correct?

Page 352

NACHTSHEIM

MS. GARCIA: Object to the form of the question, misstates the record and lack of foundation.

THE WITNESS: Correct.

BY MR. SACCHET:

Q. If we could turn to the third page of the study.

A. (Complies.) 408?

Q. Yes. Do you see the header entitled, "Statistical Analysis"?

A. I do.

Q. And it reads, "A Poisson regression model for overdispersed data was fit having the sum of bubble counts for each experimental run," paren, "ten pictures," end parens, "as the response, and the factors identified in the experimental design as predictors plus an interaction term." Do you see that?

A. I do, yes.

Q. Did you determine that a Poisson regression was the most appropriate statistical model to employ because you were dealing with counts data -- or data counts?

A. Yes.

Page 353

NACHTSHEIM

MS. GARCIA: Object to the form of the question, previously asked and answered.

BY MR. SACCHET:

Q. And that Poisson regression was a better model to use than, let's say, an ANOVA model?

MS. GARCIA: Object to the form of the question, previously asked and answered.

THE WITNESS: Yes.

BY MR. SACCHET:

Q. And if we could just turn our attention one paragraph above that, it says, "For the experimental design, a replicated and equals to 2 by 3 full factorial design was used to assess changes in bubble counts over the surgical site," correct?

A. Correct.

Q. And what were the factors?

A. So the first factor is the anesthesia screen, low grade/high grade, those are the two levels, and then there were three patient-warming devices, conductive fabric, forced-air or no warming device, and that would -- that was considered a control.

Q. Does Figure 3, directly above that paragraph,